MEASURE Human Lyo L-2
for MESURE Reagent

Lot. 216AEL (Blue Cap)

2℃～8℃ EXP. 2027.06.

Component	Analytical value		1SD	Acceptable range			Method/Instrument	Traceability
Albumin	59.4	g/L	1.98	53.5	-	65.3	BCG / Hitachi-7180	JCCRM613
	5.94	g/dL	0.198	5.35	-	6.53	±3SD range by MEASURE Reagent	(ERM DA470)
ALT	148	U/L	4.93	133	-	163	JSCC at 37°C (IFCC w/o PalP) / Hitachi-7180	JCCRM001d
	2.47	μkat/L	0.082	2.22	-	2.72	±3SD range by MEASURE Reagent	
ALP IFCC	285	U/L	14.3	242	-	328	IFCC at 37°C / Hitachi-7180	JCCRM001d (IFCC)
	4.76	μkat/L	0.238	4.05	-	5.47	±3SD range by MEASURE Reagent	
Amylase, total	382	U/L	19.10	325	-	439	IFCC at 37°C / Hitachi-7180	JCCRM001d
	6.38	μkat/L	0.319	5.42	-	7.34	±3SD range by MEASURE Reagent	
AST	230	U/L	7.67	207	-	253	JSCC at 37°C (IFCC w/o PalP) / Hitachi-7180	JCCRM001d
	3.84	μkat/L	0.128	3.46	-	4.23	±3SD range by MEASURE Reagent	
Bile Acid	116	μmol/L	11.60	81.2	-	151	Enzymatic (3-α-HDS) / Hitachi-7180	Gravimetry
	45.1	mg/L	4.507	31.5	-	58.6	±3SD range by MEASURE Reagent	
Bilirubin, direct	38.3	μmol/L	2.554	30.6	-	46.0	Enzymatic / Hitachi-7180	NIST
	2.24	mg/dL	0.132	1.79	-	2.69	±3SD range by MEASURE Reagent	
Bilirubin, total	75.4	μmol/L	2.51	67.9	-	83.0	Enzymatic / Hitachi-7180	NIST
	4.41	mg/dL	0.147	3.97	-	4.85	±3SD range by MEASURE Reagent	
Cholesterol, total	6.29	mmol/L	0.210	5.66	-	6.92	CHOD-PAP / Hitachi-7180	JCCRM223
	243	mg/dL	8.1	219	-	267	±3SD range by MEASURE Reagent	(SRM1951a)
HDL Cholesterol (*)	2.12	mmol/L	0.141	1.70	-	2.55	Direct enzymatic colorimetry / Hitachi-7180	JCCRM223
	81.9	mg/dL	5.46	65.5	-	98.3	±3SD range by MEASURE Reagent	(SRM1951a)
LDL Cholesterol	3.81	mmol/L	0.190	3.24	-	4.38	Direct enzymatic colorimetry / Hitachi7180	JCCRM223
	147	mg/dL	7.35	125	-	169	±3SD range by MEASURE Reagent	(SRM1951a)
CK	325	U/L	16.25	276	-	374	JSCC at 37°C / Hitachi-7180	JCCRM001d
	5.43	μkat/L	0.271	4.61	-	6.24	±3SD range by MEASURE Reagent	
CK-MB	74.8	U/L	9.97	44.9	-	104.7	Immunological UV / Hitachi-7180	Internal SOP
	1.25	μkat/L	0.167	0.75	-	1.75	±3SD range by MEASURE Reagent	
Creatinine	272	μmol/L	10.89	240	-	305	Enzymatic / Hitachi-7180	JCCRM521
	3.08	mg/dL	0.123	2.71	-	3.45	±3SD range by MEASURE Reagent	(ID-MS)
GGT	160	U/L	6.40	141	-	179	JSCC at 37°C / Hitachi-7180	JCCRM001d
	2.67	μkat/L	0.321	2.35	-	2.99	±3SD range by MEASURE Reagent	
Glucose	10.5	mmol/L	0.350	9.44	-	11.5	HK/G6P-DH / Hitachi-7180 HDAOS-POD / Hitachi-7180	JCCRM521
	189	mg/dL	6.30	170	-	208	±3SD range by MEASURE Reagent	(ID-MS/SRM917)
LDH IFCC	344	U/L	11.5	310	-	378	IFCC at 37°C / Hitachi-7180	JCCRM001d
	5.74	μkat/L	0.191	5.17	-	6.32	±3SD range by MEASURE Reagent	
Protein,total	95.2	g/L	3.17	85.7	-	105	Modified Biuret / Hitachi-7180	JCCRM613
	9.52	g/dL	0.317	8.57	-	10.5	±3SD range by MEASURE Reagent	(srm927)
Trglyceride	1.23	mmol/L	0.041	1.11	-	1.35	GPO/PAP	JCCRM223
	108.0	mg/dL	3.60	97.2	-	119	±3SD range by MEASURE Reagent	(ID-MS)
(TG-T)	4.87	mmol/L	0.162	4.38	-	5.35	GPO/PAP	JCCRM223
	427	mg/dL	14.23	384	-	470	±3SD range by MEASURE Reagent	(ID-MS)
Urea Nitrogen	13.3	mmol/L	0.443	12.0	-	14.6	Urease-UV / Hitachi-7180	JCCRM521
	37.1	mg/dL	1.24	33.4	-	40.8	±3SD range by MEASURE Reagent	(id-ms/srm912)
Uric acid	690	μmol/L	23.0	621	-	759	Uricase-POD / Hitachi-7180	JCCRM521
	11.6	mg/dL	0.387	10.4	-	12.8	±3SD range by MEASURE Reagent	(ID-MS)

Acceptable range : ± 3SD HDL Cholesyerol value is Provisional value

LDH, ALP : As the method has already been switched to IFCC, it has been removed from this lot.

Glucose : Added values using the HK/G6P-DH method

UMA Co,.Ltd.

Tester	Quality Control Manager	Manufacturing Control Manager
吉海	吉海	横瀬

MEASURE Human Lyo L-2

(Other Method)

Lot. 216AEL (Blue Cap)

2°C ~ 8°C EXP. 2027.06.

Component	Analytical value		U	Acceptable range	Method/Instrument	Traceability
ALT	**155**	**U/L**	**17**	**138 - 172**	IFCC 37°C with PalP	IFCC
	2.59	µkat/L	0.28	2.30 - 2.87		
Albumin	**56.7**	**g/L**	**4.8**	**51.9 - 61.5**	BCG	CRM470
	5.67	g/dL	0.38	5.29 - 6.05		
ALP	**300**	**U/L**	**27**	**273 - 327**	IFCC at 37°C	IFCC
	5.01	µkat/L	0.45	4.56 - 5.46		
Amylase, total	**372**	**U/L**	**25**	**347 - 397**	IFCC at 37°C	IFCC
	6.21	µkat/L	0.42	5.79 - 6.63		
Amylase, pancreas	**191**	**U/L**	**15**	**176 - 206**	Enzymatic colorimetry 37°C	
	3.19	µkat/L	0.25	2.94 - 3.44		
AST	**230**	**U/L**	**20**	**210 - 250**	IFCC 37°C with PalP	IFCC
	3.84	µkat/L	0.33	3.51 - 4.18		
Bilirubin, direct	**16.0**	**µmol/L**	**1.6**	**14.4 - 17.6**	Diazo	
	0.94	mg/dL	0.09	0.84 - 1.03		
Bilirubin, total	**70.2**	**µmol/L**	**8.1**	**62.1 - 78.3**	DPD	Doumas method
	4.11	mg/dL	0.47	3.63 - 4.58		
Calucium	**3.15**	**mmol/L**	**0.15**	**3.00 - 3.30**	NM-BAPTA	SRM909b
	12.6	mg/dL	0.60	12.02 - 13.23		
Chloride	**126**	**mmol/L**	**6**	**120 - 132**	Indirect ISE	Gravimetry
Cholesterol, total	**6.03**	**mmol/L**	**0.47**	**5.56 - 6.50**	CHOD/PAP	ID-MS
	233	mg/dL	18	215 - 251		
HDL Cholesterol	**1.73**	**mmol/L**	**0.22**	**1.51 - 1.95**	Direct enzymatic colorimetry	SRM1951a
	66.9	mg/dL	9	58.4 - 75.4		
LDL Cholesterol	**3.45**	**mmol/L**	**0.34**	**3.11 - 3.79**	Direct enzymatic colorimetry	SRM1951a
	133	mg/dL	13	120 - 147		
CK	**329**	**U/L**	**44**	**285 - 373**	IFCC at 37°C	IFCC
	5.49	µkat/L	0.73	4.76 - 6.23		
CK-MB	**60.0**	**U/L**	**13**	**47.0 - 73.0**	Immunological UV	ERM-AD455/IFCC
	1.00	µkat/L	0.22	0.78 - 1.22		
Copper	**30.7**	**µmol/L**	**3**	**27.7 - 33.7**	ICP-MS	SRM 3114
Creatinine	**255**	**µmol/L**	**20**	**235 - 275**	Enzymatic colorimetry	ID-MS
	2.88	mg/dL	0.23	2.66 - 3.11		
GGT	**160**	**U/L**	**10**	**150 - 170**	IFCC at 37°C	IFCC
	2.67	µkat/L	0.17	2.51 - 2.84		
GLDH	**10.3**	**U/L**	**1.0**	**9.30 - 11.3**	DGKC 37°C	
	0.17	µkat/L	0.02	0.16 - 0.19		
Glucose	**10.6**	**mmol/L**	**0.9**	**9.70 - 11.5**	HK/G6P-DH	ID-MS
	191	mg/dL	16	175 - 207		
Iron	**37.1**	**µmol/L**	**2.7**	**34.4 - 39.8**	Ascorbate/FerroZine	SRM937
	207	µg/dL	15.1	192 - 222		
Lactate	**6.03**	**mmol/L**	**0.4**	**5.63 - 6.43**	LOD/POD	Primery reference material
	54.3	mg/dL	3.6	50.7 - 57.9		
LDH	**329**	**U/L**	**40**	**289 - 369**	IFCC at 37°C	IFCC
	5.49	µkat/L	0.67	4.83 - 6.16		
Lipase	**97.9**	**U/L**	**11**	**86.9 - 109**	Enzymatic colorimetry 37°C	Roche reagent manual measurement
	1.63	µkat/L	0.18	1.45 - 1.82		
Lithium	**2.00**	**mmol/L**	**0.05**	**1.95 - 2.05**	Colorimetry	
	1.39	mg/dL	0.03	1.35 - 1.42		
Magnesium	**1.48**	**mmol/L**	**0.11**	**1.37 - 1.59**	Xylidyl-blue	Gravimetry
	3.60	mg/dL	0.27	3.33 - 3.86		
Phosphorus	**3.01**	**mmol/L**	**0.17**	**2.84 - 3.18**	Ammonium phosphomoplybdate	Primary reference material
	9.32	mg/dL	0.53	8.80 - 9.85		
Potassium	**5.97**	**mmol/L**	**0.34**	**5.63 - 6.31**	Indirect ISE	Gravimetry
Protein total	**90.3**	**g/L**	**8**	**82.3 - 98**	Biuret	SRM927c
	9.03	g/dL	0.8	8.23 - 9.83		
Sodium	**155**	**mmol/L**	**6**	**149 - 161**	Indirect ISE	Gravimetry
Theophyline	**127**	**µmol/L**			KIMS	Gravimetry
Total Bile Acid	**120**	**µmol/L**	**21**	**99 - 141**	Enzymatic endpoint	
	46.8	mg/L	8.19	38.6 - 55.0		
Trglyceride	**4.57**	**mmol/L**	**0.4**	**4.17 - 4.97**	GPO/PAP	ID-MS
	405	mg/dL	35	369 - 440		

MEASURE Human Lyo L-2

(Other Method)

Lot. 216AEL (Blue Cap)

2°C ～ 8°C EXP. 2027.06.

Component	Analytical value		U	Acceptable range			Method/Instrument	Traceability
UIBC	**45.4**	**μmol/L**	**5.8**	**39.6**	-	**51.2**	FeroZine®	Primary reference material
	253	μg/dL	32	221	-	286		
Urea	**13.0**	**mmol/L**	**1.2**	**11.8**	-	**14.2**	Urease/GLZDH	SRM909b
	36.4	mg/dL	3.4	33.1	-	39.8		
Uric acid	**660**	**μmol/L**	**62**	**598**	-	**722**	Uricase/POD	ID-MS
	11.1	mg/dL	1.04	10.1	-	12.1		
Zinc	**39.7**	**μmol/L**	**2.1**	**37.6**	-	**41.8**	ICP-MS	SRM 3168a
	259	μg/dL	14	246	-	273		

* (u) : uncertainty Acceptable range : ± 3SD

The following component will be removed from this lot and later, because the manufacturer's assigned values are not available.

Apo-A, Apo-B CHE, Estoradiol, Ferritin, Folate, HBDH, β-HCG, Homocystaine, IgA, IgG, IgM, NEFA, Osmolality, Phospholipids, Progesterone, f-T3,T3,f-T4,T4,Testosteron, Transferrin, TSH